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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
|---|-------------|-------------------------|------------------------|------------------|
| 10/659,789  | 09/10/2003  | Christopher J. Stenland | B185 1210.1 (MSC 8015) | 5573             |
| 26158   | 7590        | 09/03/2008              | EXAMINER               |                  |
| WOMBLE CARLYLE SANDRIDGE & RICE, PLLC<br>ATTN: PATENT DOCKETING 32ND FLOOR<br>P.O. BOX 7037<br>ATLANTA, GA 30357-0037 |             |                         | HORNING, MICHELLE S    |                  |
|   |             | ART UNIT                | PAPER NUMBER           |                  |
|   |             | 1648                    |                        |                  |
|   |             | MAIL DATE               |                        | DELIVERY MODE    |
|   |             | 09/03/2008              |                        | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 10/659,789             | STENLAND ET AL.     |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | MICHELLE HORNING       | 1648                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 19 March 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-18, 23-30 and 32-36 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-18, 23-30 and 32-36 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

This office action is responsive to communication filed 3/19/2008. The status of the claims is as follows: claims 1-18, 23-30 and 32-36 are under current examination.

The affidavit filed on 3/19/2008 under 37 CFR 1.131 is sufficient to overcome the Carbonell et al reference.

The following have been withdrawn due to submission of the above affidavit:

1. 35 USC 102 (e) and
2. 35 USC 103.

### ***Claim Rejections - 35 USC § 112-NEW***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.** Claim 8 recites the limitation "fumed metal oxide." There is insufficient antecedent basis for this limitation in claim 2.

### ***Claim Rejections - 35 USC § 102-NEW***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-6, 12 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6730230 (hereinafter “Cook”).**

Cook describes a method of using high density microparticles for the removal of pathogens, including prions (see whole document and Abstract). Paragraph 14 describes mixing a portion of the sample with the microparticles to bind the microparticles to the target pathogen and further separating the microparticles bound to the pathogen from the supernatant. The microparticles include metal oxides (see paragraph 26). This meets a method of preparing a solution (see claim 1). In example 2, the authors provide using a biological fluid sample of albumin that contains prions in combination with the microparticles. Note that the authors assayed an aliquot of the fluid before and after treatment and the prion agent is reduced following microparticle treatment. This teaching meets step c of evaluating the solution for the prion protein of claim 2. Paragraph 6 provides removing pathogens from whole human blood and blood components. Cook describes physical separation techniques for the removal of pathogen such as filtration (see paragraph 9) and detection assays for pathogen removal by ELISA assays (see paragraph 20). Lastly, paragraph 66 describes that the microparticles can be a part of a flow process.

***Claim Rejections - 35 USC § 103-NEW***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-18, 23-30 and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Cook, Gun'ko et al (1997) and US Patent 6150172 (Schmerr).**

The teachings of Cook are applied as they are above. Cook does not disclose, however, use of fumed silica, specific surface areas of the fumed silica, differential retention capacities of a filtration system, Western blots, fumed silica amounts, or subjecting the prion proteins associated with the metal oxides for further analysis.

Gun'ko et al characterized fumed silica and its adsorption of proteins (see whole document). The authors state that fumed silica in aqueous suspensions possesses a high adsorption ability for proteins (see Introduction). Thus, it would have been obvious to the ordinary artisan to use fumed silica in separating *any* protein, including prions, out of a solution. One would have been motivated to do so in order to produce a supernatant substantially free of the pathogen for reinsertion or transplantation into a

living organism as taught by Cook (see paragraph 69). There would have been a reasonable expectation of success given the taught success by Gun'ko et al.

Schmerr describes multiple assays in detecting abnormal prion protein, including Western blotting (see paragraphs 38-39). This assay is a known assay in the prior art for analyzing prion protein (see instant claim 18). The ordinary artisan would have routinely adjusted parameters including the surface areas and use amounts of fumed silica or the retention capacities of a filtration system to achieve optimal results. While the references above do not describe subjecting prion proteins associated with the particulate metal oxide for further analysis, this would have been obvious to do. The ordinary artisan would have been motivated to further analyze the metal oxides following separation in order to detect the infectious prion in the biological sample as well as to determine whether the metal oxides lead to the successful separation of prions or whether further adjustment of the method is necessary. Thus, the invention as a whole was clearly *prima facie* obvious to the ordinary artisan at the time the invention was made.

### ***Conclusion***

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/  
Examiner, Art Unit 1648

/Bruce Campell/  
Supervisory Patent Examiner, Art Unit 1648